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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,470	10/16/2003	Warren Stern	SOHN-P01-001	8880
28120 7590 03/16/2007 FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER SCHLIENTZ, NATHAN W	
			ART UNIT	PAPER NUMBER
			1616	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/16/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/687,470	<b>Applicant(s)</b> STERN, WARREN	
	<b>Examiner</b> Nathan W. Schlientz	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 6, 8, 9 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The examiner for your application in the USPTO has changed. Examiner Nathan Schlientz can be reached at 571-272-9924.

#### ***Acknowledgement of Receipt***

Receipt of the Applicant's Response, which was filed on 22 January 2007, in response to the Official Action dated 01 November 2006, is acknowledged.

#### ***Status of Claims***

Claims 1 was amended in the aforementioned Response. As a result, Claims 1, 5, 6, 8, 9 and 11 are examined herein on the merits for patentability, in so far as they are drawn to the elected invention. No Claim is allowed at this time.

#### ***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claim refers to Formulas I-XVIII. However, claims are to be complete in themselves. Incorporation by reference to a specific Figure, Formula, or Table is

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permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience. Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 5, 6, 8, 9 and 11 stand rejected under 35 U.S.C. 102(e) as being anticipated by WO 03/097011 A1 (hereinafter Barth et al.).

With respect to claims 1, 5, 6, 8, 9 and 11 of the instant application, Barth et al. discloses a method of treating gastroesophageal reflux disease (GERD), Zollinger-Ellison syndrome, gastric acid hypersecretion, sleep disorders, sleep apnea, snoring, nocturnal snorting and gasping, wherein said method comprises: administering a therapeutically effective amount of at least one proton pump inhibitor (i.e., an inhibitor of H<sup>+</sup>, K<sup>+</sup>-ATPase), such as lansoprazole (a.k.a., Prevacid) (abstract; page 1, lines 8, 9,

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22, 23 and 27; page 3, lines 10-13; page 8, lines 2-15; page 13, lines 20-21; page 19, lines 8-16 and 24-34; page 20, lines 1-7; page 27, lines 32-35; page 28, lines 4-7; claims 11-14 and 18).

2. The rejection of Claims 1, 5, 6, 8, 9 and 11 under 35 U.S.C. 102(a) and (e) as being anticipated by the Rubin '005 patent, is hereby withdrawn in view of the Applicant's amendment.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 6, 8, 9 and 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Ieni '221 publication, in view of either the Senior publication, or the Xiao publication.

With respect to claims 1, 5, 6, 8, 9 and 11 of the instant application, the Ieni '221 publication teaches a method of treating GERD, Zollinger-Ellison syndrome, gastric acid hypersecretion, and apnea, wherein said method comprises: administering a therapeutically effective amount of at least one proton pump inhibitor (i.e., an inhibitor of H<sup>+</sup>, K<sup>+</sup> -ATPase), including lansoprazole (a.k.a., Prevacid) and/or omeprazole (a.k.a., Prilosec) (abstract; page 1, lines 7-10 and 28-30; page 2, lines 1-3, 9-13 and 29-32;

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page 3, lines 1-3 and 20-25; page 4, lines 11-17 and 32; page 5, lines 1-3 and 31-32; page 6, lines 1-3; page 7, lines 15-19; page 8, lines 11-17; page 9, line 32; page 10, lines 1-4; page 15, lines 25-29; page 16, lines 5-20; page 17, lines 29-32; page 18, lines 1-3; claims 1, 2, 7, 8, 13 and 14). The leni '221 publication does not explicitly teach that the apneic disorder being treated is sleep apnea in particular and symptomatic snoring, which is associated therewith, as instantly claimed.

However, Senior publication teaches a method of treating GERD and obstructive sleep apnea syndrome (OSAS), wherein said method comprises: administering a therapeutically effective amount of a proton pump inhibitor, namely omeprazole (page 2144, column 1, abstract; page 2144, column 2, lines 7-9; page 2145, column 1, lines 26-27, 36-38, 43-44 and 47-56; page 2145, column 2, lines 1-9 and 55-57; page 2146, column 1, lines 1-2 and 5-7).

However, Xiao publication teaches a method of treating GERD and OSAS, wherein said method comprises: administering a therapeutically effective amount of a proton pump inhibitor, namely omeprazole (page 336, [G1373]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed that the method of treating apnea, as broadly recited, via the administration of a therapeutically effective amount of one or more proton pump inhibitor, including lansoprazole and/or omeprazole, as taught by the leni '221 publication, would have also been useful in treating specific types of apnea not explicitly recited within the leni '221 publication, such as sleep apnea, and in particular OSAS, as well as symptomatic conditions intrinsically associated therewith, such as

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snoring, as reasonably suggested by the Senior publication and the Xiao publication. One of ordinary skill in the art at the time the instant application was filed would have been motivated to treat GERD and OSAS, as well as symptomatic conditions intrinsically associated therewith, such as snoring, by substituting lansoprazole for omeprazole within the methods taught by the Senior publication and the Xiao publication, since the leni '221 publication reasonably suggests the interchangeability of lansoprazole and omeprazole for treating GERD and apneic disorders. One of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success in utilizing lansoprazole in place of omeprazole for the treatment of GERD and OSAS, as well as symptomatic conditions intrinsically associated therewith, such as snoring, since both the Senior publication and the Xiao publication teach administering a proton pump inhibitor, namely omeprazole, for the treatment of GERD and OSAS, and the leni '221 publication reasonably suggests the interchangeability of lansoprazole and omeprazole for treating GERD and apneic disorders.

Although none of the aforementioned prior art references explicitly teach a method of treating snoring, per se, the leni '221 publication teaches a method of treating apneic disorders, the Senior publication teaches a method of treating obstructive sleep apnea syndrome (OSAS), and the Xiao publication teaches a method of treating OSAS. Because snoring is a symptomatic condition intrinsically associated with OSAS, administration of a therapeutically effective amount of a proton pump inhibitor, such as lansoprazole and omeprazole, would intrinsically treat not only OSAS, but also

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symptomatic conditions intrinsically associated therewith, such as snoring, as instantly claimed.

***Examiner's Response to Applicant's Arguments***

Applicant's arguments filed 22 January 2007 have been fully considered but they are not persuasive.

1. 35 U.S.C. § 102(e) rejection of Claims 1, 5, 6, 8, 9 and 11 as being anticipated by Barth et al.

Applicant argues on pages 3-5 of the aforementioned Response that the disclosure fails to teach treatment of snoring regardless of the existence of sleep apnea. Applicant further argues that the disclosure never amounts to the teaching that certain physical signs that merely suggest the presence of sleep apnea can be treated directly with those agents. In response to Applicant's arguments, through treating patients suffering from sleep apnea, who may also exhibit the symptom of snoring, with a proton pump inhibitor, Barth et al. is inherently treating snoring. Therefore, the invention of Barth et al. anticipates the instantly claimed invention.

2. 35 U.S.C. § 103(a) rejection of Claims 1, 5, 6, 8, 9 and 11 as being unpatentable over the Ieni '221 publication, in view of either the Senior publication, or the Xiao publication.



Applicant argues on page 6 of the aforementioned Response that the references fail to teach the claimed invention, for the same reasons argued in the previous arguments for the 35 U.S.C. 102(a) and (e) rejections. In response to Applicant's arguments, similarly to the arguments above, because snoring is a symptomatic condition intrinsically associated with OSAS, administration of a therapeutically effective amount of a proton pump inhibitor, such as lansoprazole and omeprazole, would intrinsically treat not only OSAS, but also symptomatically conditions intrinsically associated therewith, such as snoring, as instantly claimed.

#### ***Contact Information***

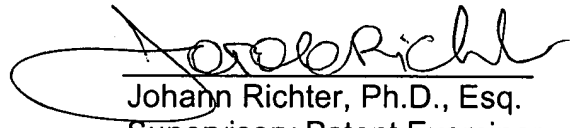
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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